K040264

APR - 2 2004

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521 - 3831

Contact Person: Sherri L Coenen

Date Prepared: February 3, 2004

Device Name

Proprietary name: Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC)

Common name: C.f.a.s. PUC

Classification name: Calibrator, Multi-analyte mixture

Device Description

The Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC) consists of a buffered aqueous solution with biological materials added as required to obtain desired component levels. Values for constituent analytes are provided in product labeling.

Intended use

C.f.a.s. (Calibrator for automated systems) PUC (Proteins in Urine/CSF) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Substantial Equivalence

The Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC) is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Roche Diagnostic Calibrator for Automated Systems (C.f.a.s.) Proteins (K011226). The intended use of both devices is the establishment of calibration curves for their respective test systems.

Substantial equivalence - similarities

The following table compares the Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC) with the predicate device.

Feature	C.f.a.s. PUC	C.f.a.s. Proteins (Predicate Device)
Intended Use	Cfas PUC is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.	Cfas Proteins is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.
Format	Liquid ready-for-use calibrator based on a buffered aqueous solution. Concentrations of calibrator components have been adjusted to ensure optimal calibration.	Liquid ready-for-use calibrator based on stabilized human serum. Concentrations of calibrator components have been adjusted to ensure optimal calibration.
Stability	• Unopened: Stable at 2-8°C until expiration date. • Opened: Stable for 4 weeks at 2-8°C.	• Unopened: Stable at 2-8°C until expiration date. • Opened: Stable for 4 weeks at 2-8°C.
Levels	Single Level	Single Level

Substantial equivalence – differences

Comparison of proposed Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC) and predicate device.

Feature	C.f.a.s. PUC	C.f.a.s. Proteins (Predicate Device)
Matrix	Buffered aqueous solution	Stabilized human serum

Constituent Analytes

C.f.a.s. PUC	C.f.a.s. Proteins (Predicate Device)
Albumin	α1-antitrypsin
Total Protein	Antistreptolysin O
Urine/ CSF Protein	C3c
	C4
	Ceruloplasmin
	C-Reactive Protein (Latex)
	Ferritin
	Haptoglobin
	IgA
	IgG
	IgM
	Prealbumin
	Transferrin

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 2 2004

Ms. Sherri L. Coenen
Regulatory Affairs Associate
Regulatory Submissions
Roche Diagnostics Corp.
9115 Hague Rd.
Indianapolis, IN 46250

Re: K040264
Trade/Device Name: Calibrator for Automated Systems Proteins in Urine/ CSF (C.f.a.s. PUC)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: February 3, 2004
Received: February 4, 2004

Dear Ms. Coenen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040264

Device Name: Calibrator for Automated Systems Proteins in Urine/CSF (C.f.a.s. PUC)

Indications For Use:

C.f.a.s. (Calibrator for automated systems) PUC (Proteins in Urine/CSF) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040264